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May 24, 2004

Mark Rohrbaugh, Ph.D., J.D.
Director of the Office of Technology Transfer
Office of Intramural Research
National Institutes of Health
6011 Executive Boulevard, Suite 325
Rockville, Maryland 20852

Dear Dr. Rohrbaugh:

On behalf of the Biotechnology Industry Organization (BIO), I am writing to express our views regarding two petitions filed by Essential Inventions, Inc., on January 29, 2004 that request that Bayh-Dole march-in authorities authorize third parties to use patents necessary for the manufacture and sale of two drug products, ritonavir and latanoprost. The petitions assert that both products were developed with assistance from NIH funding mechanisms. Both petitions take the position that the prices for the drug products in the U.S. are unreasonable, and that this factor authorizes exercise of march-in authorities. For both legal and policy reasons, BIO strongly disagrees with the petitioners' view that march-in powers should be used to impose price controls.

BIO is a trade association representing more than 1,000 biotechnology companies, academic institutions, state biotechnology centers and related organizations in the United States. Our members are involved in the research and development of health-care, agricultural, industrial and environmental biotechnology products and as such rely heavily on strong, predictable patent protection around the world. The vast majority of our members have no products on the market: they have patents as their sole assets. Small biotechnology companies use these patent assets to generate the hundreds of millions of dollars necessary to develop and commercialize a biotechnology product. While federal funding of preliminary research is critical to new product discovery, it is private sector funding that enables the development of a biotechnology product. Private sector investors are more likely to invest in product development when they can expect a return on their investment. Thus, any action by the government that undermines the ability of patent holders to exercise their patent rights is of concern to BIO.

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Success of Bayh-Dole

For over two decades, the Bayh-Dole Act has been the cornerstone of sustained progress in the U.S. biotechnology industry, facilitating a remarkably productive partnership between government, academia and industry. As NIH itself has recognized, "[f]ederally funded biomedical research, aided by the economic incentives of Bayh-Dole, has created the scientific capital of knowledge that fuels medical and biotechnology development. American taxpayers, whose lives have been improved and extended, have been the beneficiaries of the remarkable medical advances that have come from this enterprise." [1] According to the Association of American Universities, domestic universities obtained an average of fewer than 250 patents per year prior to Bayh-Dole.[2] Fewer than 5 percent of the 28, 000 patents being held by federal agencies had been licensed compared with 25 percent to 30 percent of the small number of federal patents for which the government had allowed companies to retain title to the invention. By fiscal 2002, survey results showed that two decades of Bayh-Dole had increased the number of university patents issued annually to over 3600 and over 4600 new licenses and options were reported by 219 institutions.[3]

The Bayh-Dole Act has been instrumental in bringing together the public sector and private sector to move innovative federally funded biotechnology from the bench to the bedside. It has done so by encouraging the licensing of federally funded inventions to private enterprise. Since Bayh-Dole's enactment, technology partnerships have led to the founding of more than 1,100 companies based on NIH and university research. More than 370 biotechnology products have been commercialized since the Act's passage. NIH has concluded that "[c]urrent practices in technology transfer have yielded a dramatic return to the taxpayer through the development of products that, without the successful public-private relationship, might not be available."[4] Moreover, Bayh-Dole's technology transfer policies have benefited American universities, which according to one survey received $1.337 billion in gross income from patent licenses in fiscal 2002.[5] This revenue helps to fund new research and training programs at these institutions.[6]

Legal Analysis

The Bayh-Dole Act permits the government to "march-in" and force a patent holder to grant third-party licenses if the patent holder is not taking "effective steps to achieve practical application of the subject invention" or if "action is necessary to alleviate health or safety needs."[7] Neither the plain meaning of the Act, its legislative history nor the

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[1] Department of Health and Human Services, National Institutes of Health, A Plan to Ensure Taxpayers' Interests Are Protected Part F (July 2001), *available at* http://www.nih.gov/news/070101wyden.htm.
[2] Association of American Universitites, *University Technology Transfer of Government-Funded Research Has Wide Public Benefits* (June 2, 1998), at http://www.aau.edu/research/TechTrans6.3.98.html.
[3] Association of University Technology Managers, AUTM Licensing Survey: FY 2002, Survey Summary at 12, available at http://www.autm.net/surveys/02/2002spublic.pdf.
[4] A Plan to Ensure Taxpayers' Interests Are Protected, supra Part F.
[5] AUTM Licensing Survey: FY 2002, Survey Summary, supra at 18.
[6] A Plan to Ensure Taxpayers' Interests Are Protected, supra Part C.2.a.
[7] 35 U.S.C.§ 203(a)(1), (2).

public policies underlying it contemplate use of the march-in authority because of the price of a commercially available product. Yet the march-in petitions suggest that "open licenses" should be granted if prices of commercially available products are higher in the United States than in other countries. Such an interpretation of the Act is without precedent or legal basis.

The report of the Senate Judiciary Committee explained that the Bayh-Dole Act "is designed to promote the utilization and commercialization of inventions made with government support."[8] Accordingly, the Senate bill authorized NIH to take action through the exercise of march-in rights only in the rare case "when the invention is not being used and it appears that there is a public need to use the invention."[9] By contrast, the committee report makes no mention the use of march-in rights as a tool for insuring "reasonable" prices.

The Act's co-authors, former Senators Birch Bayh and Bob Dole, have stated that the law "did not intend that government set prices on the resulting products." Indeed, the Act's authors pointed out that "[t]he law makes no reference to a reasonable price that should be dictated by the government." Furthermore, "[t]his omission was intentional; the primary purpose of the act was to entice the private sector to seek public-private research collaboration rather than focusing on its own proprietary research."[10]

The petitions urge an inappropriate use of march-in powers to impose price controls on products developed with the aid of federal funds. The Bayh-Dole Act's overriding benefit to the public is to make it possible for early-stage research to be leveraged into initial funding for the creation of private companies that will commercialize new products. Simply put, it was never the intention of Congress that the march-in powers of Bayh-Dole Act be used as a method of price setting. To the contrary, Bayh-Dole's march-in authority allows the federal government to compel licensing of a federally funded invention only if the government believes that (1) the patent owner has not commercialized the invention in a reasonable time, (2) a public health need is not being met by the recipient of the federal grant, or (3) a public noncommercial use requires licensing. These measures were included to ensure that the overall goal of the Act--to spur the interaction between public and private research to benefit the public--would be met. Not one word of the march-in provision, or Bayh-Dole's legislative history, suggests that the price charged for a product serves as a basis for exercising march-in rights.

Previous NIH Positions Reject Use of Price Controls

NIH has already concluded that Bayh-Dole does not contemplate the imposition of price controls. In 1995, NIH reversed an attempt to impose a "reasonable pricing" requirement on parties to its Cooperative Research and Development Agreements ("CRADAs").

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[8] S. Rep. No. 96-480, at 3 (1979).
[9] Id. At 18.
[10] Birch Bayh & Bob Dole, Letter to the Editor, Our Law Helps Patients Get New Drugs Sooner, Wash. Post, April 11, 2002 at A28.

Looking back on this experiment, NIH acknowledged that the policy "had the effect of posing a barrier to expanded research and development and, therefore, was contrary to the Bayh-Dole Act."[11] When NIH removed the reasonable price barrier, the number of CRADAs promptly increased.[12]

NIH has likewise previously presented its views on the important policy considerations raised by any grant of march-in rights. In rejecting the march-in petition of CellPro, Inc. in 1997, NIH recognized that the uncertainty created by an exercise of march-in rights could "have far-reaching repercussions on many companies' and investors' future willingness to invest in federally funded medical technologies." Numerous universities and university groups, similarly cognizant of the dangerous uncertainty created by a march-in, opposed the CellPro petition.[13] Many of these groups have already begun voicing their disapproval of the recent march-in petitions, warning that "[t]he ability of universities to make their federally funded technologies available to the public would be undermined, and the incentive for private sector to invest in federally funded discoveries would be removed."[14]

In denying CellPro's petition, NIH was particularly "mindful of the broader public health implications of a march-in proceeding, including the potential loss of new health care products yet to be developed from federally funded research." Its written decision emphasized that "[t]he patent system, with its resultant predictability for investment and commercial development, is the means chosen by Congress for ensuring the development and dissemination of new and useful technologies. It has proven to be an effective means for the development of health care technologies."[15]

In October 2000, Congress instructed NIH to "prepare a plan to ensure that taxpayers' interests are protected" in light of "the mounting concern over the cost to patients of

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[11] A Plan to Ensure Taxpayers' Interests Are Protected, *supra* Part C.6.

[12] *Id.* Part C.6 & App. 4.

[13] See Letter from Gerhard Casper, President, Stanford University, to Harold Varmus, Director, NIH (June 10, 1997); Letter from David J. Ramsay, President, University of Maryland at Baltimore, to Harold Varmus, Director, NIH (July 10, 1997); Letter from Richard K. Koehn, Vice President for Research, The University of Utah, to Donna E. Shalala, Secretary, Department of Health and Human Services (July 11, 1997); Letter from E. Gordon Gee, President, The Ohio State University, to Harold Varmus, Director, NIH (July 21, 1997); Letter from Cornelius J. Pings, President, Association of American Universitites, to Harold Varmus, Director, NIH (May 30, 1997); Letter from Jlordan J. Cohen, President, Association of American Medical Colleges, to Harld Varmus, Director, NIH (May 30, 1997); letter from Milton Goldbert, President, Council on Governmental Relations, to Harold Varmus, Director, NIH (June 26, 1997).

[14] Letter from National Association of State Universities and Land-Grant Colleges, Association of American Universities and American Coucil on Education to Mark Rohrbaugh, Director of the Office of Technology Transfer Center, NIH 2 (April 22, 2004); *see also* Letter from Joseph P. Allen, President , National Technology Transfer Center, *supra*; Letter from Katharina Phillips, President, Council on Governmental Relations, to Mark Rohrbaugh, Director of the Office of Technology Transfer, NIH (April 5, 2004) (stating that any "change in march-in authority or in expanding their exercise by government agencies could result in the loss of the very delicate balance of rights and obligations between the three partners – government, universities and industry - which has been the basis for the success of this legislation").

[15] Determination in the Case of Petition of CellPro, Inc., http://www.nih.gov/news/pr/aug97/nihb-01.htm

therapeutic drugs."[16] NIH's response to this Congressional directive emphasized the incredible success of the system created by the Bayh-Dole Act and concluded that "contravening the provisions of Bayh-Dole may have a deleterious effect on biotechnology development."[17] The same report matter-of-factly observed that "neither NIH nor universities have a role in drug pricing."[18]

Conclusion

In the biotechnology industry, the vast majority of funding necessary to develop new products comes from the private sector. But private sector investors will not invest in the development of research that they do not believe will yield a return on their investment. As such, the exercise of march-in powers to set price controls would defeat the overarching goal of the Act—which is to facilitate commercialization of government funded research.

As the public debate continues on the use of march-in authorities, NIH must be careful not to alter the Bayh-Dole landscape in such a way as to introduce a level of uncertainty that would lead private enterprise to withdraw from the Bayh-Dole equation. Because the Bayh-Dole Act was never intended as a price-control mechanism, any interpretation allowing price-based march in would destroy the essential fabric of the Act.

For the reasons outlined in this letter, BIO urges the NIH to (1) adopt a policy that makes it clear that a company's pricing decision does not serve to trigger march-in authorities under Bayh-Dole; and (2) deny both petitions submitted by Essential Therapeutics.

Thank you for the opportunity to provide comments on this important matter. Please call me at (202) 962-9215 or Lila Feisee, BIO's Director for Intellectual Property, at (202) 962-9502 to discuss any questions you may have.

Sincerely,

Stephan E. Lawton
Vice President & General Counsel

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[16] A Plan to Ensure Taxpayers' Interests Are Protected, *supra* Part A.
[17] *Id.* Part F.
[18] *Id.* Part D.1.